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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**REGION 10 HANFORD/INL PROJECT OFFICE**
309 Bradley Boulevard, Suite 115
Richland, Washington 99352

August 30, 2007

John Sands, Project Manager
River Corridor Baseline Risk Assessment
Richland Operations Office
U.S. Department of Energy
P.O. Box 550
Richland, Washington 99352

Re: EPA Comments on "Risk Assessment Report for the 100 Area and 300 Area Component of the River Corridor Baseline Risk Assessment," DOE/RL-2007-21, Draft A

Dear Mr. ~~Sands~~ John:

The U.S. Environmental Protection Agency has reviewed the subject document and is enclosing our comments.

If you have any questions, please feel free to contact Larry Gadbois at (509)376-9884.

Sincerely,

Larry Gadbois

Larry Gadbois
Project Manager

Enclosure:

cc: Gabe Bohnee, NRTC Chair
John Price, Ecology
Jill Thomson, WCH
Susan Leckband, HAB
Russell Jim, YN
Stuart Harris, CTUIR
Ken Niles, ODOE
Admin. Record: 100 & 300 Areas

**EPA Comments on "Risk Assessment Report for the 100 Area and 300 Area Component of the River Corridor Baseline Risk Assessment," DOE/RL-2007-21, Draft A, dated June 2007**

General Comments

1) DOE and its contractors have had a difficult task of performing and presenting a very complex risk assessment. The assessment is well organized and efficiently presents a large quantity of relevant data. The level of organization and documentation (i.e., inclusion of all of the key exposure and toxicity parameters, risk equations, and supporting documents) enhances the transparency of the assessment. Thanks for your work on this project.

2) Draft A is not amenable to a detailed review of the numeric results.
Very soon into the review of this document the EPA noted that risks portrayed for some of the waste sites, as determined in this RCBRA, were much higher than presented in the cleanup verification packages (CVPs) for these same waste sites. The data for each waste site used in the calculation of risk for the waste site was not included with the document. The EPA is aware that the data used for this RCBRA is reportedly on-line, but the user interface was too difficult to use to extract the waste site data used in the RCBRA and work the data through the RCBRA evaluation process in order to determine how much of the difference (between the RCBRA and the CVP) in risk is due to the data used and how much is due to the risk calculation process. On July 13, 2007, the EPA suggested that DOE take two sites (such as 116-F-14 and 100-F-35) and do a comparison of the RCBRA process and data with the CVP process and data. DOE and its contractors responded that this could be helpful but to date EPA has not seen the comparison we suggested. This would be a good addition to the document and the approach would be helpful to answer many of the draft questions circulated within the Hanford Advisory Board.

3) At the public workshop on July 25, 2007, DOE's contractors explained several known problems with the data used in the RCBRA. For example: (1) data collected in the waste sites before completion of the remedial action was used in the RCBRA risk calculations of post remediation conditions. This would lead to erroneously high risk results. (2) Sample data from deep vadose zone (more than 15 feet below ground surface) was included in the RCBRA risk calculations as if the data was from the shallow zone. This would lead to erroneously high risk results. (3) There were very high risks calculated in the RCBRA associated with fish consumption due to detection limit problems for PCBs and some PAHs. Because of this detection limit issue, on July 14, 2007, both Ecology and EPA directed DOE to conduct additional sampling to answer the organics risk issue. In late August the Tri-Parties met to discuss a draft sampling plan to better address both PCB and arsenic risks. That sampling should be performed and the data used in the next revision to this risk assessment document.

In the public workshop the WA State Department of Health illustrated another data error. It was explained to the participants that the Native American scenario calculated a dose

as high as 130 mRem/year due to Am-241. As described in the workshop, all data in the RCBRA assessment for Am-241 were non-detects. As pointed out in the workshop by the state, there is no reason to believe that there is any Am-241 in the fish.

Because there are multiple known data problems with the Draft A document already known to DOE and the document authors, the EPA did not bother evaluating the specific results relative to the existing conceptual model of risk from these assessment areas present in other Hanford documents.

4) Beginning on page ES-2 there are multiple instances wherein the CLUP and the national monument are inaccurately described and the inaccurate description is provided as a basis for DOE to make statements such as: "The assumptions underlying these hypothetical uses and exposure scenarios may be inconsistent with intended current and future land uses," and "DOE neither agrees with nor endorses the premises or conclusions of the risk analyses for these hypothetical site uses." All such portions of the document should be removed.

Based on discussions with DOE over the past two months, EPA knows that DOE isn't inclined to oblige the simple request to remove all such portions of the document. Therefore the EPA provides additional justification to help DOE understand the inappropriateness of these portions of the RCBRA.

The RCBRA document states that (page ES-2) "The...CLUP...and...the Hanford Reach National Monument, all establish future land uses for the Hanford Site." This statement could be revised to be accurate with two changes. The first change is to state that the CLUP is applicable while DOE owns/manages the property. It does not apply to future land owners. The CLUP identified itself as expiring in 2049, and the associated NEPA ROD is considered to have a much shorter lifespan. The second change to the statement should be that the Monument includes a very narrow strip of land on the south and west edge of the river such that most of the waste sites and groundwater contamination discussed in this RCBRA are not within the Monument. In a sense it is good that DOE broached the Monument designation in this document because land immediately adjacent to a national monument (i.e waste sites included in the RCBRA) is highly desirable for development and enhanced human use.

The RCBRA document states that (page ES-2) "The land-use designations identified in the CLUP and the National Monument are the basis for some of the human exposure scenarios evaluated in the report." To be accurate, two additional ideas should be added. The 100 Area CERCLA RODs which DOE has signed up to have cleanup levels based on a rural residential exposure scenario for the 100 Area and a portion of the 300 Area and unrestricted use chemical cleanup criteria from MTCA. The second change that would make this RCBRA document more accurate is that the remaining portion of the 300 Area is being cleaned up in accord with CERCLA RODs for industrial use, as approved by the Tri-Parties.

The RCBRA document states that (page ES-2) "Other human-use scenarios, such as industrial...rural-residential...have been evaluated as a sensitive analysis." As noted in the preceding paragraph of this comment, scenarios which have been selected in CERCLA RODs and have been the basis of 100s of millions of dollars of Hanford cleanup each year for many years should not be described as "sensitive analysis" scenarios.

The RCBRA document states that (page ES-2) the "(CTUIR) scenario, are not allowed by...the National Monument." A better explanation of how DOE reaches that conclusion would be helpful given the following statement from the Presidential proclamation which created the monument "Nothing in this proclamation shall enlarge or diminish the rights of any Indian tribe."

5) Table ES-1 The HI values for Rural-Residential fish ingestion scenario are 10x fold higher than the CTUIR scenario. Please verify.

6) Page ES-4, Human Health Risks, and elsewhere.
The document states "A series of hypothetical exposure scenarios were evaluated..." Human and eco risk assessment scenarios by design are hypothetical. The premise of a scenario is that IF a human and other biota were exposed in the manner described by the scenario, using generally conservative dose response assumptions, the risk to the individual is calculated. The scenarios provide valuable information to the cleanup program to guide an effective cleanup that reduces risks. It isn't appropriate to continually refer to the exposure scenarios as "hypothetical."

7) Page ES-5, middle paragraph
This paragraph discusses the various exposure paths in the different scenarios. It would be good to cross check the summary within the paragraph with the actual scenarios. For example, it states that Rural-Residential and the CTUIR scenarios also incorporate exposure via a variety of foodstuffs." In fact, other scenarios (such as recreational) incorporate foodstuffs. The last sentence of the paragraph states this, but it wasn't included in the sentence quoted herein. Perhaps some restructuring of the paragraph would resolve this issue.

8) Table ES-1
Providing the "punch line" of the risk assessment in numerical form in the executive summary without sufficient context supports the actions of people who function with partial information. This table is the epitome of that concern with the executive summary. Other examples include the lists of waste sites with the highest calculated risk. I believe many of these are the results of data errors discussed in EPA's first comment. But data errors aside, these lists of highest risk waste sites without being in context give an inaccurate message to the reader. For example, a 300 Area waste site that was cleaned up to industrial-use cleanup levels would be expected to not perform well against a more conservative scenario. That information is not very helpful in cleanup decision making. If a 300 Area site that was to have been cleaned up to industrial use cleanup levels does poorly in this risk assessment under an industrial use evaluation, that would be valuable

to cleanup decision making. The general issue of the executive summary was a significant topic during the July 25, 2007 public workshop, and a significant re-write would be appropriate.

9) Executive Summary, last sentence.
This sentence describes the risk from the river effluent pipelines under an avid recreational scenario. Since this scenario is different from other the other scenarios describes in the executive summary and the document, if the scenario is mentioned it should be described.

10) Page 1-3
The document states that "Remedial actions use the 'observational approach.' which relies on the existing knowledge combined with a 'characterize and remediate in one step' methodology." That is not a good depiction of the observational approach. In fact, a waste site is initially characterized based on site specific information and/or information from analogous sites to form a conceptual model, an appropriate remedial alternative for that site or other discovery sites which fit that conceptual model is selected, contingency planning is performed, and during remediation data is collected to confirm that the site continues to fit the conceptual model and selected remedy, or if site conditions are sufficiently different then the remedy for the site is re-evaluated. The web site www.epa.gov/fedfac/documents/pilot.pro.htm would be a helpful tip to the reader to understand the observational approach. In short, there is a lot more initial planning of the remedial action for a waste site than is suggested by the quote from this document.

11) Page 1-3
This document contains sweeping incorrect statements about scenarios in this document and existing CERCLA decision documents and presents and uses those inaccurate statements to conclude that the scenarios do not support the CLUP and that the CLUP is the only document supported by DOE. In addition to EPA's first comment on this topic regarding the executive summery, page 1-3 of this document states "no decisions on final land uses had been made then the Interim Action RODs for the 100 Area were written." That is not true. For example, DOE's 5-year review of the Hanford site mentions three RODs and seven ESDs since the November 12, 1999 CLUP ROD.

Another incorrect statement in this risk assessment document: "unrestricted use was evaluated via a hypothetical rural resident, a reasonably maximally exposed individual who would spend his life on the site." In fact, the rural resident scenario used in the 100 Area RODs is 30 years exposure period, and 20% of that time is spent off-site. The cleanup levels for chemicals use MTCA's unrestricted exposure which typically is 6 years exposure to a child.

12) Page 1-4
The document states "As noted above, there are two key CERCLA ecological risk assessments at the Hanford Site." "Large area" would be a better term than "key."

13) Page 1-4, section 1.4, 2nd paragraph
The document cites EPA guidance for the definition of baseline (in short, risk absent any actions), but then incorrectly presents a different definition as "Although a baseline risk assessment typically implies that no remediation has occurred." In fact, the baseline risk assessment identifies the risk that could result, under that scenario, from a subsequent no-action decision.

14) Page 1-15
Reference is made to "Field Sampling" in Section 1.2.4 – this should be 1.5.5.

15) Page 1-6, 1st full paragraph
This risk assessment document states that it included data from a listed set of other concurrent risk assessments. Notably absent from that list is the concurrent 300-FF-5 risk assessment. Was that data included? (If not, why not.) Note the first paragraph on page 1-12 regarding other risk assessments states that "As data and methodologies are developed for each assessment, they are being shared and used by other assessments as appropriate."

16) Section 1.5.3, 1st paragraph
Regarding HSRAM, the last sentence of the first paragraph of Section 1.5.3 says HSRAM "served as the basis for development of the specific requirements of the RCBRA." This should be phrased as "served as the basis for development of risk assessments used for site remediation." HSRAM is an important part of the history of Hanford risk assessments and how we got to where we are. Note that Section 1.6.1 and Section 5, which give the summary of the risk assessment approach used now for RCBRA, lists only current EPA and MTCA guidance.

17) Page 1-12, last paragraph of section 1.5.3
The document states "other projects such [as] the Sitewide Monitoring Program and the Orphan Sites program are filling in the gaps between the risk assessment study boundaries." Gaps in risk assessments have been a contentious issue at Hanford for many years. EPA is one of many entities asking DOE to perform risk assessments such that there are no gaps in risk assessments. This is a disconcerting statement.

18) Page 1-14, last paragraph of section 1.5.4.2
The document states "Data collected for the Inter-Areas shoreline assessment are considered supplemental to the 100 Area and 300 Area Component of the RCBRA." It isn't obvious to the reader what that means. (It is included, it isn't, it is included but not evaluated...) It would be helpful to state what "considered supplemental" means.

19) Page 1-18 Correct double negative: "(4) very high, indicating a distinctly pathological condition indicating that tissues is not likely to be unable to recover."

20) Page 1-19 Correct reference to MIS Sample from 1.2.6 to 1.5.6.

21) Page 1-22, section 1.6.1.1

EPA Region 10 guidance (1991f) should be added to this list.

22) For information to be used in Hanford's CERCLA remedial decision making process, it needs to be included in the Hanford administrative record. This document does not include the underlying sample data. Both the document and the underlying data (and future revisions) need to placed into the administrative record. In accord with paragraph 114 of the TPA, DOE shall maintain the administrative record.

23) Cancer risks above $10^{-2}$
Although greater uncertainty is likely associated with estimating cancer risks above $10^{-2}$, the relative ranking of these risks should not be censored. The assessment should calculate and present values and relative ranking of the hundreds of risks currently denoted as "$> 10^{-2}$".

Throughout the assessment, cancer risk is calculated using the simple, linear equation, but the magnitude of risks merit using the following adjusted logarithmic equation and explanatory text:

The linear cancer risk equation is valid only for risks below one in a hundred ($10^{-2}$). For risks above $10^{-2}$, the following one-hit equation should be used (U.S. Environmental Protection Agency Office of Solid Waste And Emergency Response, 1989): The one-hit model is based on the concept that a cancer can be induced after a single susceptible target or receptor has been exposed to a single effective dose unit of a carcinogen (U.S. Environmental Protection Agency, 1992).

One-Hit Equation: $\text{Cancer Risk} = 1-(e^{-(\text{Chemical Intake} \times \text{CSF})})$

Generalizations about the protective nature of cancer risk assessment should describe arsenic and radionuclides as significant exceptions to the rule (Sections 5.5.3 and 5.7.9.3). Text from the first paragraph on page 5-104 would add context to the beginning of the toxicity discussion. Cancer slope factors for radionuclides and arsenic are based on human epidemiologic data and are important exceptions to the "UCL .95" basis for many other cancer slope factors. Suggested example text:

CSFs used to estimate cancer risks for non-radionuclides are typically upper $95^{th}$ percentile confidence limits of the increased probability of contracting cancer per unit of dose over a lifetime. CSFs are based on human studies (e.g., observational epidemiology often from exposed workers), or more frequently, from experimental animal data.

The text makes frequent use of the following phrases, which could be deleted or replaced with active verbs without any loss of information (see hyper-links to Phrases to Avoid and EPA - Plain Language):

"it should be noted that..." - noted appears 25 times
"it is important to note..." - this phase appears 14 times

24) Page 1-22 Section 1.6.1.1 Human Health Risk Assessment Guidance and Compliance.
The following references appear redundant:

- *Risk Assessment Guidance for Superfund (RAGS) – Volume I: Human Health Evaluation Manual, Part A (Interim Final)* (EPA/540/1-89/001 [EPA 1989])
- *Risk Assessment Guidance for Superfund (RAGS) – Volume I: Human Health Evaluation Manual, Part A* (EPA/540/1-89/002)

Suggested additional reference: Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (U.S. Environmental Protection Agency, 2005c)

Verify the toxicity for tetrachloroethylene (CAS 127-184). Verify integrity of toxicity data.

This error was initially identified during review of the 300 Area Groundwater Risk Assessment and it was repeated in this assessment. Additional quality control measures should be taken to verify the integrity of the toxicity database. The chemical listed for this CAS number is named "tetrachloroethene" and its toxicity values differ from the toxicity values currently verified against the RAIS website on July 25, 2007.

Example toxicity values from Appendix G:

| Analyte | CasNumber | Type | SFo | RfDo | SFi | RfDi | SFd | RfDd | |
|---|---|---|---|---|---|---|---|---|---|
| Tetrachloroethene | 127-18-4 | | organic | NA | 0.01 | NA | 0.01 | NA | 0.01 |

Comparison to Risk Assessment Information System MetaData from Oak Ridge Laboratory:
http://rais.ornl.gov/cgi-bin/tox/TOX_select?select=nrad

- All superscripts are hyperlinked to the Oak Ridge National Laboratory Risk Assessment Information System (ORNL-RAIS)

| Chemical | CAS # | Inhalation RfC - Chronic ($mg/m^3$) | Ref. | Inhalation RfD - Chronic (mg/kg-day) | Ref. | Oral RfD - Chronic (mg/kg-day) | Ref. | Inhalation SF $(mg/kg\text{-}day)^{-1}$ | Ref. | Oral SF $(mg/kg\text{-}day)^{-1}$ | Ref. |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Tetrachloroethylene | 127184 | 6.00E-01 [v] | | 1.71E-01 [v] | | 1.00E-02 | IRIS | 2.07E-02 [u] | | 5.40E-01 [ai] | R9/CA |

25) Page 1-24, section 1.6.2.1
EPA Region 10 guidance should be added. "EPA Region 10 Supplemental Ecological Risk Assessment Guidance for Superfund", EPA 910-R-97-005, June, 1997

26) Page 2-3, last sentence on the page
The document states "Only low-level waste is known to have been disposed in the solid waste burial grounds." This is not true. Items other than low-level waste have been removed. Please look at the waste that has already been discovered during the remediation of the burial grounds. The remained of the sentence after what has been quoted here is also not true and should be removed or extensively modified.

27) Page 2-4, 1st full paragraph
The document states that the EPA 2000 ROD directed that remedial actions dispose of waste at the ERDF. Please check of the ROD states ERDF or other facility as appropriate. Please use the correct text from the ROD.

28) Page 2-7, section 2.1.2
This paragraph about the bias for action is well written. Thanks.

29) Page 2-8, 1st paragraph.
Again, the CLUP is discussed and inaccurately presented. It would be good to note that cleanups that are protective under a more intensive exposure scenario are also protective to a less intensive exposure scenario. So that the fact that the land use scenario DOE selected once in its ROD for the CLUP which is applicable during DOE site management, is less sensitive to contamination that the land use scenarios DOE has selected many times in many CERCLA RODs which apply during and after DOE's site management should not be presented as the RODs are inconsistent with the CLUP. Cleanup as defined in the CERCLA RODs will support the CLUP's vision of land use and the CERCLA RODs' vision of reasonably anticipated future land use.

Using the though from the previous paragraph, the document could be rewritten as "The rural-resident exposure scenario supports the DOE Preferred Alternative land-use alternatives..."

30) Page 2-8, 2nd paragraph
It would be good to remove the contractor language from the first sentence of this paragraph.

31) Page 2-8, 3rd paragraph
The document states "Virtually all the currently known CERCLA waste sites in the areas are covered by an interim action ROD." That sentence should be removed. In fact there are well over 100 discovery sites that need to be added via an ESD to the 100 Area remaining sites ROD.

32) Page 2-8, last paragraph
Consider changing the document to read "However, this assumption is evaluated in this risk assessment and will be reevaluated in the RI, as some interim action RODs..."

33) Page 2-8 to 2-9

Consider changing the document to read "additional human heal exposure scenarios (i.e., a Native American scenario and recreational scenarios that include hunting and fishing) have been defined since the development of the first interim action RODs." Note that version of the scenarios identified were developed in 1996-1997 which precedes all but the earliest Hanford RODs. (Please see the CRCIA document, published in final version in early 1998.)

34) Page 2-10, section 2.1.3
This section begins with a discussion of the 300-FF-1 operable unit. It would be good to point out that this remedial action was done in accord with a final ROD. It would be good to then do a global search of "interim" and delete where appropriate. There has been one 300 Area operable unit, and three 100 Area operable units covered by final RODs. This risk assessment repeatedly discusses the whole river corridor as being an interim ROD driven response only. Also, for this 300-FF-1 operable unit, it would be informative to tell the reader that there has been a construction completion report for this operable unit.

35) Page 4-17 Update discussion of iron toxicity to reflect the current provisional peer-reviewed toxicity value of 0.7 mg/kg-day (U.S. Environmental Protection Agency, Stifelman, Klotzbach, Ingerman, Thayer & Diamond, 2006).

36) Table 4-12 Please add key to abbreviations as footer (on all pages) to this and other multi-page tables.

37) Page 4-21 Section 4.3.8
It would be good to have a table showing the risk associated with these six radionuclides under the different exposure scenarios. This helps put Hanford-added risk in context. Those who want to know total site risk could use this information.

38) Page 5-38 Provide rationale for using 75$^{th}$ percentile values in place of 95$^{th}$ percentile values for time spent at home in the yard.

39) Page 5-39 "Sweat lodge" was intended; "seat lodge" was used.

40) Page 5-45, Section 5.5.3 Chemical Cancer Risk

40.1) The discussion at the bottom of page 5-45 states, "EPA believes that the underlying mechanisms of carcinogenesis imply that there is no threshold of exposure (U.S. Environmental Protection Agency Office of Solid Waste And Emergency Response, 1989)." This should be updated to include information in EPA's 2005 Guidelines for Carcinogen Risk Assessment (Section 3.3) http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=116283 regarding the appropriate application of nonlinear extrapolations to lower doses in the dose-response assessment, as an option to the linear approach under certain circumstances (U.S. Environmental Protection Agency, 2005a). See also the related discussion in section 2.B., Dose-Response Assessment, in "Implementation of the Cancer Guidelines and Accompanying

Supplemental Guidance – Science Policy Council Cancer Guidelines Implementation Workgroup Communication I: Application of the mode of action framework in mutagenicity determinations for carcinogenicity" http://epa.gov/osa/spc/pdfs/CGIWGCommuniation_I.pdf (U.S. Environmental Protection Agency, 2005b).

40.2) In the first complete paragraph, second sentence, on page 5-46, the term "mutagenic carcinogens" should be changed to the more accurate description "carcinogens that have a mutagenic mode of action." (U.S. Environmental Protection Agency, 2005d).

40.3) The second complete paragraph on page 5-46 incorrectly interprets EPA's observation in the *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (Supplemental Guidance), (http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=160003), that "the acute dosing studies have limitations that were sufficient to decide that they should not be included in the quantitative adjustment of cancer potency" to mean that there should be no adjustment at all for those chemicals that were determined to be carcinogenic via a mutagenic mode of action by acute dosing studies only (U.S. Environmental Protection Agency, 2005d). The observation in fact means that *chemical-specific* adjustments could not reliably be obtained from such studies, and therefore, the default age-dependent adjustment factors (ADAFs) to chemical-specific cancer potency factors should be applied in these cases. As indicated in *Implementation of the Cancer Guidelines and Accompanying Supplemental Guidance – Science Policy Council Cancer Guidelines Implementation Workgroup Communication II: Performing Risk Assessments that include Carcinogens Described in the Supplemental Guidance as having a Mutagenic Mode of Action* (Communication II), http://epa.gov/osa/spc/pdfs/CGIWGCommunication_II.pdf, chemical-specific adjustments to cancer potency for early-life exposure are recommended at this time only for vinyl chloride (Farland, 2006). For the other 11 carcinogens listed in the Supplemental Guidance (see Tables 4,6, and 7), it is recommended that ADAFs be applied to those with cancer potency values available on IRIS, viz., benzidine, benzo[a]pyrene, diethylnitrosamine and demethylnitrosamine. The exception to this, as described in Communication II, is that ADAFs should also be applied to other carcinogenic PAHs that are evaluated relative to benzo[a]pyrene, by making the adjustments to the benzo[a]pyrene slope factor prior to using relative potency factors to estimate risks from exposure to the other carcinogenic PAHs (Farland, 2006).

40.4) The 12 carcinogens identified in the Supplemental Guidance as having mutagenic modes of action are not a comprehensive list. Additional carcinogens have been identified in IRIS and the Superfund Technical Support Center's Provisional Peer-Reviewed Toxicity Profiles for 4,4' methylene-bis(2-chloroaniline), 1,2-dibromo-3-chloropropane and coke oven emissions as having mutagenic modes of action (U.S. Environmental Protection Agency, 2006a; U.S. Environmental Protection Agency, 2006b; U.S. Environmental Protection Agency, 1994). It is expected that more will be so identified in the future (U.S. Environmental Protection Agency, 2007). It is

recommended that the IRIS files be consulted for each carcinogenic COPC at the site to determine whether a mutagenic mode of action has been determined to pertain to the COPC, and if so, whether chemical-specific or default ADAFs should be applied when there is early-life exposure to the chemical. This recommendation does not apply to the 12 carcinogens identified in the Supplemental Guidance, as the IRIS files may not yet have been revised to include the identification of these carcinogens as having mutagenic modes of action.

41) Page 5-78 Is the elevated thallium in the reference area natural? Additional explanation would be helpful. If the thallium is anomalous, then it has potential to skew comparison between reference and operational areas.

42) Page 5-98 Move "Low" from the "Exposure Scenario" column to the "Intensity of Exposure" column.

43) Page 5-104 Suggest:

However, arsenic in fish tissue is not predominantly in the elemental form, which is the basis for the oral cancer slope factor used in the calculation of cancer risk via fish ingestion. Instead, most of the arsenic in fish tissue is organic arsenic species such as aseno-sugars, monomethylarsenic acid or dimethylarsenic acid, which are considered to be less toxic than inorganic arsenic.

44) Page 5-106 Suggest adding a statement indicating that the permeability of a sweat lodge is not known.

45) Page 5-123, Figure 5-5: In the right column, second row "Use No Value" should be changed to "Use Value".

46) Tables 5-25a, and comparable tables for the other scenarios.
It would help to add a footnote that these numbers include the risk from background with the exception of K-40, Ra-226, Ra-228, Th-228, Th-230, and Th-232.

47) Tables 5-26a, and comparable tables for the other scenarios.
It would help to add a footnote that these numbers do not include the risk from background.

48) For tables 5-25a thru 5-38b it would be good to not if these cancer risks are from radionuclides only, or chemicals plus radionuclides.

49) Table 5-30 and others: The RME HI ratio is listed as "1" or "1.E+OO". Is the latter the same as the former? Also, these ratio may be better conveyed as a figure to highlight the relative deviations from a ratio of 1 among the various waste sites.

50) Appendix G-1 – The column labels for the human health toxicity values are not correctly aligned.

51) A focused review of the ecological risk assessment portion was done with the primary goal of looking for consistency with EPA Guidance and secondarily to provide any technical comments. After review of this document EPA concludes that it is not in conflict with the EPA Guidance on ecological risk assessment (contingent on satisfactory resolution of comments and document revision).

52) This document is presented as a "baseline ecological risk assessment" (BERA), however, it is primarily an ecological risk assessment (ERA) conducted on already remediated areas. From a process standpoint this is an ERA. While this ERA is baseline for subsequent RODs, to many readers the term "baseline" suggests pre-remediation. The issue is one of expectations of the ERA not necessarily the details and ties into subsequent comments about clarity..

53) One of the most important problems within this document, and arguably an inconsistency with guidance is an overall lack of clarity. One of the objectives of the Superfund Guidance on ERA (EPA, 1997) as well as the 1995 memo from the US EPA Administrator, Carol Browner, on risk assessments (Browner,1995) is the development of a clear understanding of what is being done within the risk assessment and why it is being done that way. Things that would improve the clarity of this document would be:

- consider a title change to indicate that this is not a pre-remediation BERA;
- a presentation of what the basis was for the remediation of the areas (what risks existed before remediation and how they were determined);
- a presentation of what the risk based goals for the remediation were, both in terms of the assessment endpoints and the contaminant based goals;
- a presentations of the expectations for the role of this document within the Site process;
- concise presentations of the assessment endpoints, the associated measurement endpoints and the exposure assessment assumption and the technical justifications.

54) Within the ERA it is nearly impossible to reproduce the hazard quotients reported. Presumably all of the input parameters were agreed to by the stakeholders, as this is accordance with the EPA Guidance (EPA, 1997). This information should be present in the work plan and associated documents leading to this ERA report. A detailed compilation of this information is not necessary, however a summary would improve the document and add "guidance consistency".

55) A technical issue with the current ERA is the use of a hazard index (HI) for ecological risk.

It has been established that chemicals can and do interact and modify the effect of other chemical exposures. It is known that chemicals can interact additively, antagonistically (less than additive) or synergistically (greater than additive). Known interactive effects between chemicals is the basis behind the development and use of pesticide formulations.

The objective of many pesticide formulations is to increase the effectiveness (the toxicity) of the pesticide formulation (mixture) on target species, or alternately to limit the effect on non-target species. In the field of pharmacology chemical interactions are also a major issue with potential drug interactions, both positive interaction (increased effectiveness of the drugs) or negative side effects or ineffectiveness of the medication.

There is however a major distinction between the use of interactive/cumulative effects in pharmacology and pesticides and the application of chemical interactions for cumulative risk assessment. This distinction primarily relates to our level of knowledge. In pharmacology and pesticide application we know how the chemicals work, the biochemical mechanisms, chemical pathways and the severity of the effects. We also know the exposure pathway and the doses, because we design how the chemicals are administered or applied and we specify the dose or the application rate. However, within the area of hazardous waste risk assessment, we develop a Site conceptual model to assist us in evaluating the potential exposure pathways and to estimate potential exposure levels. We typically do not know what the exposures actually are and for many contaminants we do not truly understand the mechanisms of the adverse ecological effects and we have very limited information of interactive effects. This lack of knowledge greatly reduces our ability to quantitatively evaluate the interactions of chemical exposures within risk assessments.

Within risk assessments some "risks" may be combined with confidence, for example the Hazard Quotient (HQ) for Cd and U may be added (for mammalian and avian assessment endpoints) as both elements impact the kidney in the same way. However, even in this example there is a question of the potency, are Cd and U just as toxic as each other, if they are not then the Hazard Index (HI) of just these two contaminants over estimates the risk. This example highlights an issue in risk assessment where the assessment of cumulative risk is desired. Risk estimates are typically unit-less but they are relate to the toxic mechanism of the toxicity reference value used, and are not independent of the toxicity benchmark or the slope of the toxicity curve and/or "potency". These issues are discussed in the EPA Risk Assessment Guidance (USEPA 1989).

EPA guidance does indicate that cumulative risk may and sometimes should be calculated. However, the Guidance states that the calculations of cumulative risk should be done only at the screening stage (for Human Health) and if the HI indicates a potential risk further risk assessment work must be done to determine if the HI is technically sound. Additionally, the Guidance suggests that HIs are calculated on COPCs, not all chemicals for which analyses were conducted.

In ecological risk assessments the development of a HI is problematic, especially with metals and at the screening stage. Screening levels for ecological risks are frequently below background in many areas of the country. Therefore, at the screening level most elements will not initially screen out. If an HI is calculated at this point in the ERA process, the resulting HI gives no information unless the HI is less than 1 (which is very unlikely strictly from the prospective of the mathematics). For this reason, in ecological risk assessment, HIs should only be calculated when there is a known interaction and

common mode of action between the contaminants. This does not mean that the issue of cumulative risk should not be acknowledged, but rather that we have no technically valid means of quantifying that cumulative risk.

In practice, some of our HQs are the same as a HI; for example PAHs/BNA, the toxicity benchmarks for PAHs used in ERAs is typically expresses as either total PAHs and/or as high molecular weight and low molecular weight PAHs. This is done because we do not have ecologically based toxicity benchmarks for all of the PAHs, but we do know that many have a similar mode of action for many environmental receptors (non-specific narcosis). In this instance we calculate an HQ form the sum of contaminants, as opposed to calculating individual HQ values by compound and summing them to get effectively an HI although it is still called an HQ.

In summary, the issue of cumulative stress being a real and potentially important issue may be appropriately acknowledged within an ERA (Screening level ERA or BERA). However, there are currently no accepted means of quantifying cumulative risk, except when the mechanism of toxicity is known and a common mode of action exists. Even in these instances there is uncertainty with the risk estimate because differences in contaminant potency may exist, which is not accounted for within any HQ value. While acknowledgement that cumulative risk may exist at a Site is appropriate; the calculation of HIs is frequently not technically justifiable and is unlikely to assist in remedy decision making.

56) A second outstanding technical issue is the use of ½ the detection limit for all non-detects within the ERA.

A long standing issue within risk assessments is how to evaluate non-detect data within the exposure assessment and risk characterization. There have been numerous methods proposed in the literature for addressing the use of non-detect data within data sets. In practice the method selected for use of non-detect data is dependent upon the objective of any particular study or data assessment. Ultimately the objective of all of the various methods is to minimize the impact of the non-detects on statistical assessments of the data set and the resulting conclusions. For example elimination of non-detects from a data set will tend to increase the estimates of the mean of the data set while the use of a zero value (for non-detects) will decrease the mean estimate.

Within risk assessments environmental media contaminant concentrations are used to estimate exposure point concentration estimates. If maximum media concentration data is being used as the exposure point estimate then non-detect values should not impact the assessment, unless the sample quantification limits (SQL) is above the toxicity benchmark or threshold for adverse effects, and/or there are no actual detected concentrations. This circumstance should not occur if the SQL required in the risk assessment was specified within the data quality objectives of the QWAP for Site investigations. If the SQL is at or below the no effect level, there should be limited need to evaluate non-detects data (all HQ values for compounds below the SQL should be less than 1). If there is a HI (hazard index) which will be calculated or if a toxicity

benchmark is based upon a summation of the concentration of individual compounds, as is done with PAHs, there may be a need to consider the non-detect data.

Within the human health risk assessment Guidance (US EPA 1989), it is suggested that ½ the SQL is the default value to be used within the risk characterization. Alternate estimates may be appropriate if they can be technically justified. For example 1/10 the SQL has been used in ecological risk assessments for organic compounds when it can be stated that, if the compound was present above 1/10 the SQL a "J" value (estimated concentration below the SQL) would have been reported.

In the EPA Guidance for risk assessments within Superfund (USEPA, 1989) there is a discussion the when non-detect values may be used and when they may not be used within the exposure estimates. In brief, the Guidance indicates that if there is information to indicate that a chemical does not exist at a Site (or within the area used to develop the exposure point estimate), the chemical should not be included within the risk assessment. The information used to exclude a compound may be chemical process information, records on chemical use, or simply that the compound has not been detected at the Site/location above the SQL. There is no technical justification to include a non-detect data point only because the compound is within the list of compounds for which analyses are being conducted.

57) A third technical issue with the ERA relates to the selected TRVs used to calculate the HQ values. As stated above, the TRVs should have been agreed to by the Stakeholders. However, there is no apparent consistent pattern to the TRVs selected; some are relatively conservative (for example the avian Ni TRV appears to be below what I would use as a NOAEL), while others are relatively not conservative (the mammalian U TRV is above what has been used as a LOAEL). Consider including an appendix which summarizes the TRV selection process and the justification for each of the TRVs, with reference to the documents which contain the primary selection process.

There appears to be the use of area use factors (AUFs) within the HQ calculations, both spatial and temporal use factors. This approach should have been agreed to by the stakeholders. The use of AUFs within the ERA is acceptable when agreed to by the stakeholders. However, there needs to be a presentation of what the AUFs are (the numeric values) and the technical justification of why that AUF was appropriate. An AUF of 1 as it is the most conservative but just, or more importantly, it allows for definitive statements about areas and/or concentrations. Since this document largely addresses "remediated areas" an AUF of 1 would seem to be a functional approach to concluding that there is not residual Site related ecological risk. As with the TRV issue, an appendix with a discussion of the AUF selection by assessment endpoint and/or measurement endpoint would be useful. The utilization of large AUF is a controversial issue and can become a guidance consistency issue.

58) In summary, I believe there are large areas for improvement within the presentations of this ERA. Additionally, the resolution of many of the "clarity issues" raised within these comments has a direct bearing on the conclusion that this document "follows" EPA

Guidance. The current conclusion is that (with a couple of exceptions), the document does appear to follow "Guidance"; however, this conclusion is premised upon the assumptions stated in the preceding comments. The major exception to the issue of guidance consistency is the use of HI scores. While the use of HIs is accepted within EPA Guidance, it is only accepted at the screening level, unless there is clear toxicological justification for the use of a HI score in the risk characterization of the baseline risk assessment.

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